

REMARKS

Status of Claims

Claims 1 – 73 were original in the application. Claims 1 – 34, 41 – 45, 48, and 57 – 73 have been withdrawn and cancelled without prejudice. Claims 35, 37 – 39, 49, 52, 53, and 56 have been currently amended. Claims 35 – 40, 46, 47, and 49 – 56 as amended or originally filed are submitted for examination on the merits.

Rejection Pursuant to 35 USC 102

Claims 35 – 40, 46, 47, and 49 – 56 were rejected as being anticipated by Balbierz U.S. Patent 6,770,070.

In regard to claim 35, the single examined independent claim, the Examiner cited Balbierz as disclosing an apparatus of electroforming tissue comprising: means for creating stress in the tissue (see electrode 18 in figures 9 and distal end of device i 6 in figures 5j; means for causing a current to flow in the tissue (power source 20 in figure 7 and electrode 18 in figures 9) while the created stress is present to change shape of the tissue or material parameters of the tissue (inherent).

Balbierz is an RF ablation apparatus having a lung biopsy device having an energy delivery device, including at least one electrode designed to be deployed into target lung tissue, and a sensor. Balbierz is not an apparatus for electroforming tissue. The purpose of the electrode 18 in Balbierz is to penetrate tissue and provide a means for applying an RF energy to the tissue to perform complete ablation or necrosis. Col. 6, lines 19 – 25; Col. 14, lines 51 – 35. The dictionary meaning of “ablation” is surgical

removal or loss of a part by melting or vaporization. "Necrosis" means localized death of living tissue.¹ The word, "stress" does not appear in Balbierz, nor does the concept of creating stress on tissue. The concept of shaping tissue is utterly absent from any disclosure in Balbierz. Balbierz is totally silent in regard to any electroforming method or device. Further, there is no disclosure whatsoever in Balbierz of any means for causing a current to flow in the tissue while the created stress is present to change shape of the tissue or material parameters of the tissue. Power source 20 of Balbierz delivers an RF current to kill the tissue and to vaporize it. Power source 20 and electrode 18 do not change shape of the tissue or material parameters of the living tissue without necrosis or ablation. The teachings of Balbierz are utterly useless and worthless with respect to the claimed invention and do not in any sense disclose it.

It is not enough to find a reference where an electrode is utilized in a body and where energy is applied through the electrode to the body and then contend that the prior art thus disclosed electroforming cartilage under stress to reshape it or otherwise alter its tissue characteristics. The claimed functions are the defining limitations and are completely absent from the Balbierz disclosure.

Claim 35 is a claim in which each of the elements is a means elements. Pursuant to 35 USC 112, sixth paragraph, the function performed by the means is the defining limitation of the means.² 35 USC 112, sixth paragraph, cannot be ignored by mischaracterizing the defining function in a means element as a nonstructural use. It is

¹ Merriam-Webster Online Dictionary: www.m-w.com/cgi-bin/dictionary

² "An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

error to base a rejection of a combination of means elements on prior art structure for performing ***other functions*** and to ignore the distinguishable defining functions of the claimed means elements. The functions recited in the claim must be given full defining weight in the claim construction.

The electrode 18 does not create stress in the tissue to temporally define and maintain a predetermined shape of the tissue while a current is applied to the tissue while stressed through the stress-defining electrode to permanently change shape of the tissue or material parameters of the tissue without necrosis or ablation. Electrode 18 of Balbierz is a penetrating electrode which functions solely to deliver energy to an internal body tissue. No shapes are defined temporarily which are thereafter rendered permanent shapes of the tissue. It is sheer speculation whether there is any stress which is maintained while current is applied. It cannot be ignored that Balbierz obliterates the tissue so that it no longer exists. Permanent retention of a temporarily applied shape is a physical impossibility. Balbierz's structural elements do not perform the same intended function or lend themselves in any sense to the same use even with the most strained inherent construction. Balbierz ablates the tissue or removes it. There is nothing left to have a shape, but perhaps shapeless cinders which are subsequently absorbed by the body.

Claims 36 – 62 depend directly or indirectly on claim 35 and are allowable therewith. Claims 36 – 62 are also allowable for such further grounds of distinction as described below.

In regard to claim 36 the Examiner contends that Balbierz discloses a means for

causing a direct current of a predetermined ("preset", col. 24:46) polarity (monopolar, bipolar changes in col. 24:46-53) to flow (power source 20) in the tissue to mediate the tissue.

Claim 35 calls for a means for causing a direct current of a predetermined polarity to flow in the tissue to mediate the tissue. A "preset amount of energy" col. 24:46 is not direct current. Balbierz uses only RF current and never discloses any use of direct current. The "monopolar" and "bipolar" energy delivery does not refer to the polarity of a direct current or for that matter to polarity of even an RF current. Monopolar energy delivery refers to delivery through a device which has one electrode on the delivery end of the device, and bipolar energy delivery refers to delivery through a device which has two electrodes on the delivery end of the device. This terminology is common through biomedical engineering and does not refer to polarity of a current.

The Examiner also appears to contend that claim 36 is not allowable because it employs "intended use language". To the extent understood this ground of rejection flies in the face of section 112, sixth paragraph, and is an error as a matter of law.

In regard to claim 37, the Examiner contends that Balbierz discloses a means for mechanically applying force (see distal end of device 16 in figures 9) to the tissue to create external stresses applied to the tissue.

Claim 37 calls for a means for mechanically applying force to the tissue to create external stresses applied to the tissue to temporally define and maintain a predetermined shape of the tissue. Balbierz discloses no such means. It is not disclosed that the penetrating needle 16 either applies any stress to the shape of the

tissue, but instead pierces the tissue and certainly needle 16 does not temporally define and maintain a predetermined shape of the tissue. A needle creates a hole in the tissue so that the tissue assumes its unperturbed original shape around the needle.

In regard to claim 38, the Examiner contends that Balbierz discloses a means for changing material parameters (tissue puncturing edges - see distal end of device 16 in figures 9) of the tissue to create internal stresses in the tissue.

Claim 38 calls for a means for changing material parameters of the tissue to create internal stresses in the tissue. The characteristics of the material of the tissue or cartilage, i.e. its internal microscope form and nature, are changed to create internal stresses in the cartilage to permanently change its shape to the predetermined shape. The ablation of Balbierz performs no such operation. Reducing tissue to ashes by ablation doesn't permanently change its shape to a predetermined shape, but removes the tissue so that "shape of the tissue" no longer has any meaning.

In regard to claim 39, the Examiner contends that Balbierz discloses a means for causing a current to flow (see electrode 18 in figures 9 and power source 20 in figure 7) in the tissue.

Claim 39 further defines the means for changing material parameters of the tissue as comprising means for causing a current to flow in the tissue. Electrode 18 in Fig. 9 is an ablation electrode for causing an RF current in tissue to vaporize it. The means disclosed in the specification which changes the parameters of the bulk material of the tissue or cartilage is defined by the disclosure in paragraph [014] as well as

numerous other locations a “. . . process of tissue electroforming and (a disclosure of) how shape changes in cartilage can be produced by the application of direct current (DC).”

In regard to claim 40, the Examiner contends that Balbierz discloses a means for comprising monitoring (324 in figure 27; see col. 18:7-27) the stresses in the tissue and means for controlling (338 in figure 27, 350,329,346) the current flowing in the tissue according to the stresses therein.

Balbierz never mentions stress in materials in any context. Sensor 324 is a temperature or impedance sensor for measuring the degree of ablation of the tissue. “The control signal is used by power circuits 340 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor 324.” Col. 24, lines 7 - 10. There is no sensor in Balbierz that monitors the stresses in the tissue or controls the current flowing in the tissue according to the stresses.

In regard to claim 46, the Examiner contends that Balbierz discloses a means for monitoring color of the tissue as caused by a chemical dye (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) disposed therein.

While Balbierz discloses chemical or optical sensors without further specification or detail, there is no disclosure of a means for monitoring the stresses in the tissue let alone a stress sensor which monitors color of the tissue as caused by a chemical dye disposed therein. Nonspecific reference to a chemical or optical sensor with respect to

a temperature or impedance sensor does not serve as an enabled disclosure of all conceivable chemical or optical sensors for all conceivable contexts, uses or applications.

In regard to claim 47, the Examiner contends that Balbierz discloses a means for monitoring color (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) of the tissue as caused by electroplating a material thereon.

Balbierz is utterly silent with respect to any disclosure of any color sensor as caused by electroplating a material on the tissue. Electroplating is never mentioned in any context in Balbierz, let alone use of electroplating in stress measure in tissue.

In regard to claim 49, the Examiner contends that Balbierz discloses a means for applying voltage pulses (power source 20) of the same polarity to form a DC pulse train.

There is no means disclosed in the RF ablation device of Balbierz to apply voltage pulses of the same polarity to form a DC pulse train. This is not intended use language, but is a structural through function explicitly allowed under 35 USC 112, sixth paragraph. In a means claims, the disclosed structure for performing the defining function is what I claimed and there is utterly no disclosure in Balbierz disclosing any structure for applying voltage pulses of the same polarity to form a DC pulse train. The prior art structure of Balbierz is not capable of performing the intended use. Hence, it does not meet the claim.

In regard to claim 50, the Examiner contends that Balbierz discloses a means for

applying a first sequence of voltage pulses of the same polarity (power source 20) and means for applying a second sequence (power source 20) of voltage pulses of the opposite polarity (power source 20) to form a complex DC pulse train.

Once again, there is nothing disclosed in the RF ablation device of Balbierz to apply a first sequence of voltage pulses of the same polarity and a second sequence of voltage pulses of the opposite polarity to form a complex DC pulse train. This is not intended use language, but is a structural through function explicitly allowed under 35 USC 112, sixth paragraph. In a means claims, the disclosed structure for performing the defining function is what I claimed and there is utterly no disclosure in Balbierz disclosing any structure for applying first and second sequences of voltage pulses of different polarities to form a complex DC pulse train. Balbierz does not include a DC pulse generator for even apply one sequence of pulses, let alone two different ones. The prior art structure of Balbierz is not capable of performing the intended use. Hence, it does not meet the claim.

In regard to claim 51, the Examiner contends that Balbierz discloses the means for applying a first and second sequence of voltage pulses to provide a net charge cancellation when integrated over an application time.

Again, there is nothing disclosed in the RF ablation device of Balbierz to apply first and second sequence of voltage pulses to provide a net charge cancellation when integrated over an application time. This is not intended use language, but is a structural through function explicitly allowed under 35 USC 112, sixth paragraph. In a means claims, the disclosed structure for performing the defining function is what I

claimed and there is utterly no disclosure in Balbierz disclosing any structure for applying first and second sequence of voltage pulses to provide a net charge cancellation when integrated over an application time. Balbierz does not include a DC pulse generator for even apply one sequence of pulses, let alone two net-charge canceling ones. The prior art structure of Balbierz is not capable of performing the intended use. Hence, it does not meet the claim.

In regard to claim 52, the Examiner contends that Balbierz discloses a means for flowing current from a positive electrode to obtain tissue compression in the proximity of the positive electrode. The Examiner contends that Balbierz inherently includes tissue compression at the positive electrode.

Balbierz is silent as to any direct current induced tissue compression. In fact, RF current does not inherently result in any tissue compression. This is not intended use language, but is a structural through function explicitly allowed under 35 USC 112, sixth paragraph.

In regard to claim 53, the Examiner contends that Balbierz discloses a means for flowing current from a negative electrode to obtain tissue lengthening in the proximity of the negative electrode. The Examiner contends that Balbierz inherently includes tissue lengthening at the negative electrode.

Balbierz is silent as to any direct current induced tissue lengthening. In fact, RF current does not inherently result in any tissue lengthening. This is not intended use language, but is a structural through function explicitly allowed under 35 USC 112, sixth

paragraph.

In regard to claim 54, the Examiner contends that Balbierz discloses a means for (16, 18, 20) tension, compression, shear or combinations thereof in the tissue.

The Examiner repeats the grounds of rejection for claim 53 against claim 54 with respect to alleged inherency of tissue lengthening. Such a rejection is irrelevant as to claim 54. This is not intended use language, but is a structural through function explicitly allowed under 35 USC 112, sixth paragraph.

In regard to claim 55, the Examiner contends that Balbierz discloses a means for applying a DC voltage (20) for a predetermined ("preset", col. 24:46) application time across two paired conductive elements (18 in figure 12) in contact with the tissue.

Balbierz discloses a pair of RF delivery devices 18 and 18' in Fig. 12, but neither device 18 or 18' is a means for applying a DC voltage as alleged in the Examiner's rejection.

In regard to claim 56, the Examiner contends that Balbierz discloses means for (12 with 16) placing a solid conductive element (18) in contact with the tissue, including solid conductive elements composed of metals or conductive polymers (see col. 15:53-55).

Balbierz discloses a solid conductive element in contact with the tissue, but not

one made of conductive polymers and certainly not in the context of applying DC currents for tissue reshaping.

Applicant respectfully requests advancement of the claims to allowance.

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